



12-11-03

12-11-03

✓

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Stavrianopoulos et al

Serial No. 10/713,183

Group Art Unit: Not yet known

Filed: November 14, 2003

Examiner: Not yet known

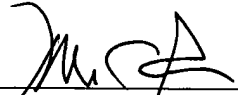
Title: NOVEL PROCESS, CONSTRUCT AND CONJUGATE FOR PRODUCING MULTIPLE
NUCLEIC ACID COPIES

TRANSMITTAL
INFORMATION DISCLOSURE STATEMENT

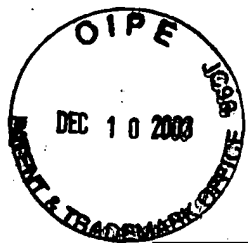
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§ 1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

EXPRESS MAIL CERTIFICATE	
"Express Mail" Label No.:	<u>EL634886170US</u>
Deposit Date:	<u>December 10, 2003</u>
I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
 Ronald C. Fedus Reg. Exhibit 32,567	<u>DEC 10 2003</u> Date

Enz-52(D2)(C)(D1)



Enz-52(D2)(C)(D1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Stavrianopoulos et al

Serial No. 10/713,183

Filed: November 14, 2003

Title: NOVEL PROCESS, CONSTRUCT AND
CONJUGATE FOR PRODUCING MULTIPLE
NUCLEIC ACID COPIES

Group Art Unit: Not yet known

Examiner: Not yet known

527 Madison Avenue, 9th Floor
New York, New York 10022
December 10, 2003

FILED VIA EXPRESS MAIL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§1.56 & 1.971.98

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §1.971.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following seventy-three (73) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

12/12/2003 EFLORES 00000076 051135 10713183

01 FC:1806 180.00 DA

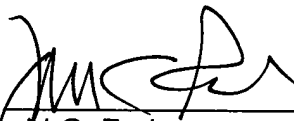
Enz-52(D2)(C)(D1)

than three months prior to the filing of this Information Disclosure Statement.

10. ☐ A check in the amount of \$180.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).
- ☒ Charge the fee under 37 C.F.R. §1.17(i)(1) to Deposit Account No. 05-1135. Order No. **Enz-52(D2)(C)(D1)**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

Dated: December 10, 2003

By: 
Ronald C. Fedus
Registration No. 32,567

Mailing Address:

ENZO LIFE SCIENCES, INC.
c/o Enzo Biochem, Inc.
292 Madison Avenue, 9th Floor
New York, New York 10022
Telephone: (212) 583-0100
Telefax: (212) 583-0150

Enz-52(D2)(C)(D1)

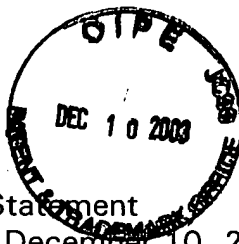
Stavrianopoulos et al

Serial No.: 10/713,183

Filed: November 14, 2003

Page 2 [Information Disclosure Statement

- December 10, 2003]



EXPRESS MAIL CERTIFICATE

"Express Mail" Label No.: EL634886170US

Deposit Date: December 10, 2003

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Ronald C. Fedus
Reg. Exhibit 32,567

DEC 10 2003

Date

1. Backman, K., European Patent Application Publication No. 0 320 308, published June 14, 1989 (**Exhibit 1**);
2. Backman, K. et al., European Patent Application Publication No. 0 439 182 A2, published July 31, 1991 (**Exhibit 2**);
3. Brakel et al., U.S. Patent Application Serial No. 07/998,660, filed on December 23, 1992 the contents of which are disclosed in European Patent Application 0 435 150 A2, published on July 3, 1991 (**Exhibit 3**);
4. Chu et al., U.S. Patent No. 4,957,858, issued September 18, 1990 (**Exhibit 4**);
5. Engelhardt et al., U.S. Patent No. 5,241,060, issued August 31, 1993 (**Exhibit 5**);
6. Engelhardt and Rabbani, U.S. Patent Application Serial No. 07/968,706, filed on October 30, 1992, now United States Patent No. 5,288,609, the contents of which has also been published as European Patent Application Publication No. 0 159 719 A2, published October 30, 1985 (**Exhibit 6**);
7. Malek, L.T. U.S. Patent No. 5,130,238, issued July 14, 1992 (**Exhibit 7**);
8. Mullis et al., U.S. Patent No. 4,683,195, issued July 28, 1987 (**Exhibit 8**);
9. Pergolizzi, Stavrianopoulos, Rabbani, Engelhardt, and Kline, U.S. Patent Application Serial No. 08/032,769, filed on March 16, 1993, published as European Patent No. 0 128 332 B1, on August 2, 1995 (**Exhibit 9**);
10. Segev, D. (1991) European Patent Application Publication No. 0 450 594, published October 9, 1991 (**Exhibit 10**);
11. Stavrianopoulos, U.S. Patent Application Serial No. 07/633,730, filed on December 24, 1990, published as European Patent Application Publication No. 0 492 570 A1 on July 1, 1992 (**Exhibit 11**);
12. Stavrianopoulos, United States Patent No. 4,707,440, issued November 17, 1987 (**Exhibit 12**);
13. Stavrianopoulos and Rabbani, U.S. Patent Application Serial No. 07/956,566 filed on October 5, 1992 (**Exhibit 13**);

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior ☐ Divisional or ☐ Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No. _____, filed _____.
4. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
 - ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.
 - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application.
 - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☒ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
 - ☐ A check in the amount of \$180.00 is enclosed in payment of the fee.

☒ Charge the fee to Deposit Account No. 05-1135, Order No. **Enz-52(D2)(C)(D1)**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

7. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
 - b. the attached petition requesting consideration of this Information Disclosure Statement; and
 - c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.
8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:
- a. ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
 - b. ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.
 - c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.
9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more

Enz-52(D2)(C)(D1)

14. Walker, G.T. and Schram, J.L, European Patent Application Publication No. 0 500 224 A2, published August 26, 1992 (**Exhibit 14**);
15. Walker, G.T. et al. European Patent Application No. 0 543 612 A2, published May 26, 1993 (**Exhibit 15**);
16. Walker, G.T., European Patent Application Publication No. 0 497 272 A1, published August 5, 1992 (**Exhibit 16**);
17. Ward et al., U.S. Patent No. 4,711,955, issued December 8, 1987 (**Exhibit 17**);
18. Wetmur, Quartin and Engelhardt, U.S. Patent Application Serial No. 07/499,938, filed on March 26, 1990, now United States Patent No. 5,958,681, issued September 28, 1999, which has also been disclosed in European Patent Application Serial No. 0 450 370 A1, published on October 9, 1991 (**Exhibit 18**);
19. Barany, F., Proc. Nat. Acad. Sci USA "Genetic disease detection and DNA amplification using cloned thermostable ligase," 88:189-193 (1991) (**Exhibit 19**);
20. Fuerst, T.R. et al., "Eukaryotic transient-expression system based on recombinant vaccinia virus that synthesizes bacteriophage T7 RNA polymerase," Proc Nat Acad Sci USA 83: 8122-8126 (1986) (**Exhibit 20**);
21. Hartley, J.L., U.S. Patent No. 5,043,272, issued August 27, 1991 (**Exhibit 21**);
22. Guatelli, J.C. et al., "Isothermal, *in vitro* amplification of nucleic acids by a multienzyme reaction modeled after retroviral replication," Proc Nat Acad Sci. USA 87: 1874-1878 (1990) (**Exhibit 22**);
23. Keller and Manak (DNA Probes, MacMillan Publishers Ltd, Great Britain, and Stockton Press (U.S. and Canada, 1989, pages 225-228) (**Exhibit 23**);
24. Karkas, J.D. et al., "Action of DNA Polymerase I of *Escherichia coli* with DNA-RNA Hybrids as Templates," Proc Nat Acad Sci U.S.A. 69(2): 398-402 (1972) (**Exhibit 24**);

25. Kievits, T., et al. "NASBA™ isothermal enzymatic in vitro nucleic acid amplification optimized for the diagnosis of HIV-1 infection," J. Virol. Methods **35**: 273-286 (1991) (Exhibit 25);
26. Kwoh, D.Y. et al., "Transcription-based amplification system and detection of amplified human immunodeficiency virus type 1 with a bead-based sandwich hybridization format," Proc Nat Acad Sci. USA., **86**: 1173-1177 (1989) (Exhibit 26);
27. Landegren, U., et al., "Ligase-Mediated Gene Detection Technique," Science **241**: 1077-1080 (1988) (Exhibit 27);
28. Lizardi et al., "Exponential amplification of recombinant RNA hybridization probes," Biotechnology **6**: 1197-1202 (1988) (Exhibit 28);
29. Mullis and Faloona, "Specific Synthesis of DNA *in Vitro* via a Polymerase-Catalyzed Chain Reaction," Methods in Enzymology **155**: 335-351 (1987) (Exhibit 29);
30. Saiki, et al., "Enzymatic Amplification of β -Globin Genomic Sequences and Restriction Site Analysis for Diagnosis of Sickle Cell Anemia," Science **230**: 1350-1354 (1985) (Exhibit 30);
31. Walker, G.T. et al., "Isothermal *in vitro* amplification of DNA by a restriction enzyme/DNA polymerase system," Proc Natl Acad Sci USA **89**: 392-396 (1992) (Exhibit 31);
32. Walker, G.T. et al., "Strand displacement amplification – an isothermal, in vitro DNA amplification technique," Nuc Acids Res. **20**: 1691-1696 (1992) (Exhibit 32);
33. Wetmur, J.G. and Davidson, N., "Kinetics of Renaturation of DNA," J. Mol. Biol. **31**: 349-370 (1968) (Exhibit 33);
34. Wu, D. and Wallace, R.B. "The Ligation Amplification Reaction (LAR) – Amplification of Specific DNA Sequences Using Sequential Rounds of Template-Dependent Ligation," Genomics **4**: 560-569 (1989) (Exhibit 34);
35. Aono et al. JP 146,299, published June 15, 1993 (Exhibit 35);
36. Auerbach et al.,. United States Patent No. 5,354,668, issued October 11, 1994 (Exhibit 36);

37. Backman et al. United States Patent No. 5,516,663, issued May 14, 1996 (Exhibit 37);
38. Bernstein et al., United States Patent No. 6,183,961 B1, issued February 6, 2001 (Exhibit 38);
39. Courey et al. "Influence of DNA Sequence and Supercoiling on the Process of Cruciform Formation," Journal of Molecular Biology 202: 35-43 (1988) (Exhibit 39);
40. Cubicciotti, United States Patent No. 5,756,296, issued May 26, 1998 (Exhibit 40);
41. Dahlberg et al., United States Patent 5,871,911, issued February 16, 1999 (Exhibit 41);
42. Dubensky, Jr. et al., United States Patent No. 5,843,723, issued December 1, 1998 (Exhibit 42);
43. Gerdes et al., United States Patent No. 5,955,351, issued on September 21, 1999 (Exhibit 43);
44. Gerwitz, United States Patent No. 5,612,212, issued March 18, 1997 (Exhibit 44);
45. Jones, United States Patent No. 6,190,889 B1, issued February 20, 2001 (Exhibit 45);
46. Kacian et al., United States Patent No. 5,399,491, issued March 21, 1995 (Exhibit 46);
47. Knorre et al. "Oligonucleotides with Highly Reactive Groups Selectively Bound By E. Coli RNA Polymerase: Identification of the Enzyme Subunits Interacting with Them and The Competitive Inhibition of Transcription," IZV SIB OTD ADAD NAUK SSR SER BIOL NAUK 0(2): 98-104 (1989) (Exhibit 47);
48. Matthews et al., "Analytical Strategies for the Use of DNA Probes," Analytical Biochemistry 169: 1-25 (1988) (Exhibit 48);

49. Meric et al., "Rous Sarcoma Virus Nucleic Acid-binding Protein p12 is Necessary for Viral 70S RNA Dimer Formation and Packaging," Journal of Virology, 60(2): 450-459 (1986) (**Exhibit 49**);
50. Ostrander et al. "Template Supercoiling by a Chimera of Yeast GAL4 Protein and Phage T7 RNA Polymerase," Science: 249: 1261-1265 (1990) (**Exhibit 50**);
51. Promega Catalog, Page 150, Figure 4G (**Exhibit 51**);
52. Reim et al., EP 0 178 863 A1, published April 23, 1986 (**Exhibit 52**);
53. Romano et al., U.S. Statutory Invention Registration Number H1,825, published on December 7, 1999 (**Exhibit 53**);
54. Urdea, United States Patent No. 5,118,605, issued June 2, 1992 (**Exhibit 54**);
55. Walker, United States Patent No. 5,455,166, issued on October 3, 1995 (**Exhibit 55**);
56. Watson et al. In Molecular Biology of the Gene, Benjamin/Cummings, Publishing, Ch 10 (1987) (**Exhibit 56**);
57. Zaichikov et al., "Study of the Elongation of Oligonucleotides Covalently Fixed at the Active Center of RNA-Polymerase," Bioorganicheskaya Khimiya 14(1):121-124 (1988) (**Exhibit 57**);
58. Pardee, et al., United States Patent No. 5,965,409, issued October 12, 1999 (**Exhibit 58**);
59. Hartley, J.L., European Patent Application 0 395 398, filed April 26, 1990 (**Exhibit 59**);
60. Feinberg, A.P., et al, "A Technique for Radiolabeling DNA Restriction Endonuclease Fragments to High Specific Activity," Analytical Biochemistry 132(1):6-13 (1983) (**Exhibit 60**);
61. Kornberg, A., et al, "DNA Replication," 2nd Edition, W.H. Freeman & Company, New York, Chapter 4, pp.150-152 (1992) (**Exhibit 61**);

62. Kwok, S., et al, "Effects of primer – template mismatches on the polymerase chain reaction: Human immunodeficiency virus type 1 model studies," Nucleic Acids Research, 18(4): 999-1005 (1990) (**Exhibit 62**);
63. Sommer, R., et al, "Minimal homology requirements for PCR primers," Nucleic Acids Research, 17(16):6749 (1989) (**Exhibit 63**);
64. Engelhardt, D., et al, European Patent Application 0 302 175, filed June 22, 1983 (**Exhibit 64**);
65. Daube, S., et al, "Functional Transcription Elongation Complexes from Synthetic RNA-DNA Bubble Duplexes," Science, 258:1320-1324 (1992) (**Exhibit 65**);
66. Tabor, S., et al, "A bacteriophage T7 RNA polymerase/promoter system for controlled exclusive expression of specific genes," Proc. Natl. Acad. Sci. USA, 82:1074-1078 (1985) (**Exhibit 66**);
67. Cook, P.R., et al, "Transcription by an immobilized RNA polymerase from bacteriophage T7 and topology of transcription," Nucleic Acids Research, 20(14):3591-3598 (1992) (**Exhibit 67**);
68. Berg, R.H., et al, International Patent Application WO 95/14789, filed November 22, 1994 (**Exhibit 68**);
69. Igarashi, K., European Patent Application 0 406 738, filed June 30, 1990 (**Exhibit 69**);
70. Gao, X, et al, "Cytoplasmic expression of a reporter gene by co-delivery of T7 RNA polymerase and T7 promoter sequence with cationic liposomes," Nucleic Acids Research, 21(12):2867-2872 (1993) (**Exhibit 70**);
71. Elroy-Stein, O., et al, "Cytoplasmic expression system based on constitutive synthesis of bacteriophage T7 RNA polymerase mammalian cells," Proc. Natl. Acad. Sci. USA, 87:6743-6747 (1990) (**Exhibit 71**);
72. Chu, B., et al, International Patent Application WO 90/02819, filed September 6, 1989 (**Exhibit 72**);
73. Wagner, T., et al, International Patent Application WO 94/26911, filed May 13, 1994 (**Exhibit 73**).

The first thirty-four (34) of the foregoing references (numbers 1-34) were cited in the specification of the instant application. References 35-37, 44, 54, and 56 are cited in Office Action mailed April 9, 1997 with respect to a parent application, serial number 08/182,621. References 38, 41, and 45-46 are cited in an Office Action mailed February 28, 2001 with respect to a divisional application, serial number 09/727,349. References 39, 43, 47, 53, 55, and 57 are cited in an Office Action mailed April 19, 2000 with respect to a parent application, serial number 09/302,816. References 40, 49, 51 were cited in an Office Action mailed January 10, 2000 with respect to a divisional application, serial number 09/302,816. References 42, 50, and 52 were cited in an Office Action mailed May 2, 2000 with respect to a divisional application, serial number 09/302,817. Reference 58 was cited in an Office Action mailed August 9, 2001 with respect to a parent application, serial number 09/302,816. References 59-69 were cited in the Search Report dated September 28, 1995 of the related European Patent Application 0 667 393. References 70-73 were cited in the Search Report dated November 20, 2003 of the divisional European Patent Application 2003-0187140.

Two (2) of the above listed 73 references are not in English, reference numbers 47 and 57. Copies of English translations are attached as Exhibits 47 and 57, respectively.

A completed Form PTO-1449 listing the 73 above-submitted documents is also attached hereto as Exhibit 74.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.

The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith,

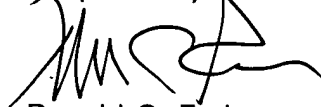
which is not intended to serve in any way as a substitute for the Examiner's own search.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither disclosed nor suggested by the documents referred to above and is thus patentably distinct thereover. Furthermore, Applicants do not believe, and do not submit, by the citation of these references, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.

The fee under 37 C.F.R. §1.17(p) for filing this Information Disclosure Statement is \$180.00. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,



Ronald C. Fedus
Registration No. 32,567
Attorney for Applicants

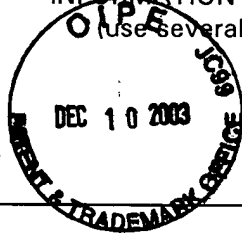
ENZO LIFE SCIENCES, INC.
c/o Enzo Biochem, Inc.
527 Madison Avenue, 9th Floor
New York, New York 10022
Tel. (212) 583-0100

Form PTO-1449 U.S. Department of Commerce

(REV. 8-83) Patent and Trademark Office

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Atty. Docket No.
ENZ-52(D2)(C)(D1)

Serial No. 10/713,183

Applicants: Stavrianopoulos, et al

Filed: Nov. 14, 2003

Group: Not yet known

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO- PRIATE
	4 9 5 7 8 5 8		Chu et al			
	5 2 4 1 0 6 0		Engelhardt et al			
	5 1 3 0 2 3 8		Malek, L.T.			
	4 6 8 3 1 9 5		Mullis, et al			
	5 2 8 8 6 0 9		Engelhardt et al			
	4 7 0 7 4 4 0		Stavrianopoulos et al			

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN- SLATION YES NO
EP 0 3 2 0 3 0 8		Backman, K.			
EP 0 4 3 9 1 8 2		Backman, K.			
EP 0 4 3 5 1 5 0		Brakel et al			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Barany, F., Proc. Nat. Acad. Sci USA "Genetic disease detection and DNA amplification using cloned thermostable ligase," 88:189-193 (1991)
	Fuerst, T.R. et al., "Eukaryotic transient-expression system based on recombinant vaccinia virus that synthesizes bacteriophage T7 RNA polymerase," Proc Nat Acad Sci USA 83: 8122-8126 (1986)
	Guatelli, J.C. et al., "Isothermal, <i>in vitro</i> amplification of nucleic acids by a multienzyme reaction modeled after retroviral replication," Proc Nat Acad Sci. USA 87: 1874-78 (1990)
	Keller and Manak (DNA Probes, MacMillan Publishers Ltd, Great Britain, and Stockton Press (U.S. and Canada, 1989, pages 225-228)
	Karkas, J.D. et al., "Action of DNA Polymerase I of <i>Escherichia coli</i> with DNA-RNA Hybrids as Templates," Proc Nat Acad Sci U.S.A. 69(2): 398-402 (1972)
	Kievits, T., et al. "NASBA" isothermal enzymatic <i>in vitro</i> nucleic acid amplification optimized for the diagnosis of HIV-1 infection," J. Virol. Methods 35: 273-286 (1991)
	Landegren, U., et al., "Ligase-Mediated Gene Detection Technique," Science 241: 1077-1080 (1988)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce

(REV. 8-83) Patent and Trademark Office

Atty. Docket No.
ENZ-52(D2)(C)(D1)

Serial No. 10/713,183

INFORMATION DISCLOSURE CITATION

(use several sheets if necessary)

Applicants: Stavrianopoulos, et al

Filed: Nov. 14, 2003

Group: Not yet known

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO- PRIATE
0 7	9 5 6 5 6 6	10/5/92	Rabbani et al			
	4 7 1 1 9 5 5		Ward et al			
	5 9 5 8 6 8 1		Wetmur et al			
	5 0 4 3 2 7 2		Hartley, J.L.			
	5 3 5 4 6 6 8		Auerbach et al			
	5 5 1 6 6 6 3		Backman et al			
	6 1 8 3 9 6 1		Bernstein et al			

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN- SLATION YES NO
EP 0 1 2 8 3 3 2		Pergolizzi et al			
EP 0 4 9 2 5 7 0		Stavrianopoulos et al			
EP 0 5 0 0 2 2 4		Walker et al			

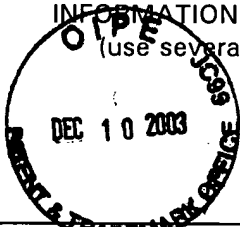
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Kwoh, D.Y. et al., "Transcription-based amplification system and detection of amplified human immunodeficiency virus type 1 with a bead-based sandwich hybridization format," <u>Proc Nat Acad Sci. USA.</u> , 86: 1173-1177 (1989)
Lizardi et al., "Exponential amplification of recombinant RNA hybridization probes," <u>Biotechnology</u> 6: 1197-1202 (1988)
Mullis and Faloona, "Specific Synthesis of DNA <i>in Vitro</i> via a Polymerase-Catalyzed Chain Reaction," <u>Methods in Enzymology</u> 155: 335-351 (1987)
Saiki, et al., "Enzymatic Amplification of β -Globin Genomic Sequences and Restriction Site Analysis for Diagnosis of Sickle Cell Anemia," <u>Science</u> 230: 1350-1354 (1985)
Walker, G.T. et al., "Isothermal <i>in vitro</i> amplification of DNA by a restriction enzyme/DNA polymerase system," <u>Proc Natl Acad Sci USA</u> 89: 392-396 (1992)
Walker, G.T. et al., "Strand displacement amplification - an isothermal, <i>in vitro</i> DNA amplification technique," <u>Nuc Acids Res.</u> 20: 1691-1696 (1992)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 8-83) Patent and Trademark Office	Atty. Docket No. ENZ-52(D2)(C)(D1)	Serial No. 10/713,183
INFORMATION DISCLOSURE CITATION (use several sheets if necessary) 	Applicants: Stavrianopoulos, et al	
	Filed: Nov. 14, 2003	Group: Not yet known

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO- PRIATE
	5 7 5 6 2 9 6		Cubiciotti			
	5 8 7 1 9 1 1		Dahlberg et al			
	5 8 4 3 7 2 3		Dubensky et al			
	5 9 5 5 3 5 1		Gerdes et al			
	5 6 1 2 2 1 2		Gerwitz			
	6 1 9 0 8 8 9		Jones			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN- SLATION YES NO
EP	0 5 4 3 6 1 2		Walker et al			
EP	0 4 9 7 2 7 2		Walker, GT			
EP	0 4 5 0 5 9 4		Segev et al			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Wetmur, J.G. and Davidson, N., "Kinetics of Renaturation of DNA," <u>J. Mol. Biol.</u> 31: 349-370 (1968)
	Wu, D. and Wallace, R.B. "The Ligation Amplification Reaction (LAR) - Amplification of Specific DNA Sequences Using Sequential Rounds of Template-Dependent Ligation," <u>Genomics</u> 4: 560-569 (1989)
	Courey et al. "Influence of DNA Sequence and Supercoiling on the Process of Cruciform Formation," <u>Journal of Molecular Biology</u> 202: 35-43 (1988)
	Knorre et al. "Oligonucleotides with Highly Reactive Groups Selectively Bound By E. Coli RNA Polymerase: Identification of the Enzyme Subunits Interacting with Them and The Competitive Inhibition of Transcription," <u>IZV SIB OTD ADAD NAUK SSR SER BIOL NAUK</u> 0(2): 98-104 (1989)
	Matthews et al., "Analytical Strategies for the Use of DNA Probes," <u>Analytical Biochemistry</u> 169: 1-25 (1988)
	Meric et al., "Rous Sarcoma Virus Nucleic Acid-binding Protein p12 is Necessary for Viral 70S RNA Dimer Formation and Packaging," <u>Journal of Virology</u> , 60(2): 450-459 (1986)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce

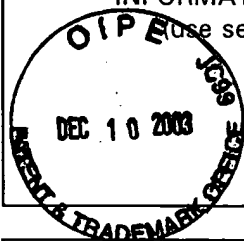
(REV. 8-83) Patent and Trademark Office

Atty. Docket No.
ENZ-52(D2)(C)(D1)

Serial No. 10/713,183

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)



Applicants: Stavrianopoulos, et al

Filed: Nov. 14, 2003

Group: Not yet known

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO- PRIATE
	5 3 9 9 4 9 1		Kacian et al			
H1	8 2 5	12/7/99	Romano et al			
	5 1 1 8 6 0 5		Urdea			
	5 4 5 5 1 6 6		Walker			
	5 9 6 5 4 0 9		Pardee et al			

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN- SLATION YES NO
JP 1 4 6 2 9 9	6/15/93	Aono et al			
EP 0 1 7 8 8 6 3		Reim et al			
EP 0 3 9 5 3 9 8		Hartley et al			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Ostrander et al. "Template Supercoiling by a Chimera of Yeast GAL4 Protein and Phage T7 RNA Polymerase," <u>Science</u> : 249: 1261-1265 (1990)
	Promega Catalog, Page 150, Figure 4G
	Watson et al. <u>In Molecular Biology of the Gene</u> , Benjamin/Cummings, Publishing, Ch 10 (1987)
	Zaichikov et al., "Study of the Elongation of Oligonucleotides Covalently Fixed at the Active Center of RNA-Polymerase," <u>Bioorganicheskaya Khimiya</u> 14(1):121-124 (1988)
	Feinberg, A.P., et al, "A Technique for Radiolabeling DNA Restriction Endonuclease Fragments to High Specific Activity," <u>Analytical Biochemistry</u> 132(1):6-13 (1983)
	Kornberg, A., et al, "DNA Replication," 2 nd Edition, W.H. Freeman & Company, New York, Chapter 4, pp.150-152 (1992)
	Kwok, S., et al, "Effects of primer - template mismatches on the polymerase chain reaction: Human immunodeficiency virus type 1 model studies," <u>Nucleic Acids Research</u> , 18(4): 999-1005 (1990)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce

(REV. 8-83) Patent and Trademark Office

Atty. Docket No.
ENZ-52(D2)(C)(D1)

Serial No. 10/713,183

INFORMATION DISCLOSURE CITATION
(use several sheets if necessary)

Applicants: Stavrianopoulos, et al

Filed: Nov. 14, 2003

Group: Not yet known

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO- PRIATE

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN- SLATION YES NO
	EP 0 3 0 2 1 7 5		Engelhardt et al			
	WO 9 0 0 2 8 1 9		Chu et al			
	WO 9 4 2 6 9 1 1		Wagner et al			
✓	WO 9 5 1 4 7 8 9		Berg et al			
✓	EP 0 4 0 6 7 3 8		Igarashi et al			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Sommer, R., et al, "Minimal homology requirements for PCR primers," <u>Nucleic Acids Research</u> , 17(16):6749 (1989)
	Daube, S., et al, "Functional Transcription Elongation Complexes from Synthetic RNA-DNA Bubble Duplexes," <u>Science</u> , 258:1320-1324 (1992)
	Tabor, S., et al, "A bacteriophage T7 RNA polymerase/promoter system for controlled exclusive expression of specific genes," <u>Proc. Natl. Acad. Sci. USA</u> , 82:1074-1078 (1985)
	Cook, P.R., et al, "Transcription by an immobilized RNA polymerase from bacteriophage T7 and topology of transcription," <u>Nucleic Acids Research</u> , 20(14):3591-3598 (1992)
	Gao, X, et al, "Cytoplasmic expression of a reporter gene by co-delivery of T7 RNA polymerase and T7 promoter sequence with cationic liposomes," <u>Nucleic Acids Research</u> , 21(12):2867-2872 (1993)
	Elroy-Stein, O., et al, "Cytoplasmic expression system based on constitutive synthesis of bacteriophage T7 RNA polymerase mammalian cells," <u>Proc. Natl. Acad. Sci. USA</u> , 87:6743-6747 (1990)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.